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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

5 June 1997

WARNING LETTER BUF 97-21

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Edward H. Knapp, Owner
Knapp's Greenwood Farm
Route 91
Fabius, New York 13063

Dear Mr. Knapp:

A tissue residue report from the United States Department of Agriculture (USDA), an inspection of your dairy operation, and related investigations by Food and Drug Administration (FDA) Investigator David M. McNew, revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act).

A food is adulterated within the meaning of Section 402(a)(2)(D) of the Act if it contains a new animal drug which is unsafe within the meaning of Section 512 of the Act. On or about 25 November 1996, you offered a cow, identified by USDA laboratory report number 212897, metal ear tag number 21ZBW6001, and your farm ear tag number 964, for slaughter for human food. USDA analysis of the tissue from this animal revealed the presence of penicillin at a level of 0.43 ppm in kidney tissue and 0.13 ppm in liver tissue. This exceeds the 0.05 ppm tolerance for penicillin in cattle and causes the food to be adulterated.

A food is adulterated within the meaning of Section 402(a)(4) of the Act if it has been held under conditions whereby it may have been rendered injurious to health. You hold animals under conditions whereby medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you fail to maintain permanent and complete treatment records and a system to review such records prior to offering cattle for slaughter for human food. You also fail to assure drugs have been used only as directed, and, if needed, extended withdrawal periods have been observed to permit depletion of potentially harmful residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

A drug is adulterated within the meaning of Section 501(a)(5) of the Act if it is a new animal drug which is unsafe within the meaning of Section 512 of the Act. Section 512, in part, deems a new animal drug unsafe unless an FDA approved application is in effect and the drug, its labeling, and its use conform to such approved application. [redacted] labeling allows a maximum daily dosage of 1 mL per 100 pounds of weight for no more than 5 days. Your use of this drug at a level of 40 mL per day in a cow weighing 1,200 pounds or less exceeds the daily dosage and adulterates the drug.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

Please note it is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for violation of the Act. The fact you caused, or participated in causing, the adulteration of an animal sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce, is sufficient to hold you responsible for violation of the Act.

You should take prompt action to correct these and all violations existing at your farm, and set up procedures whereby such violations will not recur. Failure to take such action may result in regulatory action, such as injunction, without further notice.

Please notify this office, in writing, within 15 days of the specific steps you have taken to bring your firm into compliance with the law. Your response should include each step taken, or to be taken, to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and time frame within which corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made. Your response may be directed to Raymond D. Kent, Team Leader, at the above address.

Sincerely,

Robert L Hart

Robert L. Hart
Acting District Director

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